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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/640,636	08/17/00	LEWIN D	15966-560(CU

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EXAMINER	
SPIEGLER,A	
ART UNIT	**PAPER NUMBER**
1656	7

DATE MAILED: 03/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/640,636	LEWIN ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-46 and 52-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 15-18, 21, and 54-56 drawn to methods of assessing hematopoietic status in a subject, isolated nucleic acids molecules, vectors, host cells, and kits, classified in class 536, subclass 23.1 and class 435, subclass 6, for example.

II. Claims 13-14, drawn to methods of treating a hematopoietic disorder in a subject, classified in class 514, subclass 2, for example.

III. Claims 19, 22-23, drawn to a purified polypeptide encoded by a polynucleotide and a method to detect the presence of a polypeptide, classified in class 530, subclass 300, for example.

IV. Claim 20, drawn to an antibody that binds to a polypeptide, classified in class 530, subclass 378.1, for example.

V. Claim 24, drawn to a method of modulating the activity of a polypeptide, classified in class 435, subclass 4, for example.

VI. Claims 25-26, drawn to methods of promoting migration of a hematopoietic stem cell, classified in class 435, subclass 4, for example.

VII. Claims 27-31, drawn to methods of inhibiting proliferation or differentiation of a hematopoietic stem cell, classified in class 435, subclass 4, for example.

VIII. Claim 32, drawn to a method of identifying an agent that modulates hematopoiesis using a polypeptide, classified in class 435, subclass 4, for example.

IX. Claim 33, drawn to a method of identifying an agent that modulates hematopoiesis using a hematopoietic stem cell, class undeterminable, subclass undeterminable.

X. Claims 34-36, 42-43, drawn to a chimeric polypeptide comprising a chemokine and a hematopoietic modulating sequence, and a method for detecting the polypeptide, classified in class 530, subclass 300, for example.

XI. Claims 37-40, drawn to isolated nucleic acids, vectors, and host cells, encoding a polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 536, subclass 23.1, for example.

XII. Claim 41, drawn to an antibody that binds to a chimeric polypeptide comprising a chemokine and a hematopoietic modulating sequence, and a method for detecting the polypeptide, classified in class 530, subclass 378.1, for example.

XIII. Claim 44, drawn to a method of modulating the activity of a polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 435, subclass 4, for example.

XIV. Claims 45-46, drawn to methods of promoting migration of a hematopoietic stem cell with the polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 435, subclass 4, for example.

XV. Claim 52, drawn to a method of identifying an agent that modulates hematopoiesis using a polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 435, subclass 4, for example.

XVI. Claim 53, drawn to a method of identifying an agent that modulates hematopoiesis using a hematopoietic stem cell and a polypeptide comprising a chemokine and a hematopoietic modulating sequence, classified in class 435, subclass 4, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I and XI) and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Groups (I and XI) can be used in materially different methods than the treatment methods of Group II, such as in hybridization assays.

Inventions (I and XI) and (III and X) are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups (III and X), the critical feature is a polypeptide whereas for Groups (I and XI) the critical feature is a nucleic acid. It is acknowledged that various processing steps may cause a polypeptide of Groups (III and X) to be directed as to its synthesis by a nucleic acids of Groups (I and XI), however, the completely separate chemical types of the inventions of Groups (I and XI) and (III and X) supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct,

because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions (I and XI) and (IV and XII) are separate and distinct, as the claims of Inventions (I and XI) are drawn to nucleic acids, while the claims of Groups (IV and XII) are drawn to antibodies. These are differing biochemical entities having differing biochemical properties, structures and effects. Inventions (IV and XII) would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Inventions (I and XI) and (V-IX and XIII-XVI) are separate and distinct as the nucleic acids of Groups (I and XI) are not used in the polypeptide based methods of Groups (V-IX and XIII-XVI). The two Inventions would require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions I and XI are separate and distinct as the nucleic acids of Group I are drawn to nucleic acids encoding hematopoietic polypeptide, and the nucleic acids of Group XI are drawn to nucleic acids encoding a chimeric polypeptide comprising a chemokine and hematopoietic modulating sequence. These nucleic acids have different structures and functions, and would require different searches, thus causing an undue burden on the examiner.

Inventions II and (III and X) are separate and distinct, as the claims of Group II are drawn to nucleic acids, while the claims of Groups (III and X) are drawn to polypeptides. These are differing biochemical entities having differing biochemical properties, structures and effects. Groups (III and X) would require searching in areas unrelated to nucleic acids, and as such, would require an undue burden on the examiner if not restricted.

Inventions II and (IV and XII) are separate and distinct, as the claims of Group II are drawn to nucleic acids, while the claims of Groups (IV and XII) are drawn to antibodies. These are differing biochemical entities having differing biochemical properties, structures and effects. Groups (IV and XII) would require searching in areas unrelated to nucleic acids, and as such, would require an undue burden on the examiner if not restricted.

Invention II and (V-IX and XIII-XVI) are separate and distinct as the claims of Group II are drawn to methods using nucleic acids, whereas the claims of Groups (V-IX and XIII-XVI) are drawn to methods using polypeptides. These Inventions would require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions II and XI are separate and distinct as the claims of Group II are drawn to nucleic acids encoding hematopoietic polypeptide, whereas the nucleic acids of Group XI are drawn to nucleic acids encoding a chimeric polypeptide comprising a chemokine and hematopoietic modulating sequence. These Inventions would require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions (III and X) and (IV and XII) are separate and distinct as the polypeptides of Groups (III and X) are structurally and biochemically different than the antibodies of Groups (IV and XII). While the antibodies may bind to the polypeptides of Groups (III and X), the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Inventions (III and X) and (V-IX and XIII-XVI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups (III and X) can be used in making vaccines.

Inventions III and X are separate and distinct as the polypeptides of Group III are drawn to polypeptides encoding hematopoietic polypeptide, and the polypeptides of Group X are drawn to polypeptides encoding a chimeric polypeptide comprising a chemokine and hematopoietic modulating sequence. These polypeptides have different structures and functions, and would require different searches, thus causing an undue burden on the examiner.

Inventions (IV and XII) and (V-IX and XIII-XVI) are separate and distinct as the antibodies of Groups (IV and XII) are not used in the polypeptide based methods of Groups (V-IX and XIII-XVI). The two Inventions would require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions IV and XII are separate and distinct as the antibodies of Group I are drawn to antibodies that bind to polypeptides encoding hematopoietic polypeptides, and the antibodies of Group XII are drawn to antibodies that bind to polypeptides encoding a chimeric polypeptide comprising a chemokine and hematopoietic modulating sequence. These antibodies have different structures and functions, and would require different searches, thus causing an undue burden on the examiner.

Inventions (V-IX and XIII-XVI) are unrelated. Inventions are unrelated if it can be

shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods which have different method steps, starting materials, and goals.

2. It is noted that claims 47-51 have not been ~~examined~~ included in the restriction because of an improper dependency. Claims 47-51 are drawn to methods using the polypeptide of claim 32, but claim 32 is drawn to a method of identifying an agent that modulates hematopoiesis.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the

specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

3. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XVI require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. A telephone call was made to Thomas J. Wrona on March 20, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
March 20, 2001

Kenneth R. Horlick, Ph.D.
KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1800/1600
3/21/01